

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:

Inventors: Harder et al.

Serial No.: 10/706,717

Filed: November 11, 2003

For: ENDOPROSTHESIS

Art Unit: 3773

Examiner: Melanie Ruano Tyson

REPLY BRIEF

To: Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

To the Commissioner:

This is an appeal under 37 C.F.R. §1.191 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the final rejection of claims 1-20 in the above-identified patent application.

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The final page of **Section VII** of this reply brief bears the practitioner's signature.

I. REAL PARTY IN INTEREST

The real party in interest in the present application has changed since the filing of the Appeal Brief. The real party in interest in the present application is Biotronik VI Patent AG, by assignment from Biotronik AG, executed November 14, 2008 and recorded in the United States Patent and Trademark Office at Reel 022054, Frame 0521. Biotronik AG received rights in the application by assignment from Biotronik GmbH & Co. KG, recorded in the United States Patent and Trademark Office at Reel 015018, Frame 0625. Biotronik GmbH & Co. KG obtained its rights in the application by assignment from inventors Claus Harder, Bodo Gerold, Heinz Mueller, and Bernd Heublein. The assignment from the inventors to Biotronik GmbH & Co. KG is recorded in the United States Patent and Trademark Office at Reel 014702, Frame 0746.

III. STATUS OF CLAIMS

The status of the claims in this application is:

1. TOTAL NUMBER OF CLAIMS IN APPLICATION

There are 37 pending claims in this application, numbered 1-37.

In the Office Action of February 7, 2008, the Examiner issued a final office action rejecting pending claims 1-17 and 19-35 under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu and claims 18 and 36-37 under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu in view of U.S. Patent No. 6,676,697 to Richter.

2. STATUS OF ALL OF THE CLAIMS

- A. Claims canceled: NONE.
- B. Claims withdrawn from consideration but not canceled: NONE.
- C. Claims pending: Claims 1-37.
- D. Claims allowed: NONE.
- E. Claims rejected: 1-37.

3. CLAIMS ON APPEAL

The claims on appeal are claims 1-37.

VI. GROUNDΣ OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1–17 and 19–35 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu.
2. Whether claims 18 and 36–37 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu in view of U.S. Patent No. 6,676,697 to Richter.

VII. ARGUMENTS

REPLY TO EXAMINER'S RESPONSE

In the Examiner's Answer of November 26, 2008, the Examiner maintained that U.S. Pat. No. 6,979,347 to Wu (hereinafter "Wu") discloses an endoprosthesis having a carrier structure that comprises a magnesium alloy and that it would have been obvious to a person of ordinary skill in the art to use a magnesium alloy of the composition claimed in such an endoprosthesis at the time of the invention because such alloys are well known, as shown by U.S. Pat. No 4,401,621 to Unsworth (hereinafter "Unsworth"). The Examiner contended that it would have been "within the general skill of a worker to select a known material on the basis of its suitability for the intended use as a matter of design choice." (Examiner's Answer, page 5, lines 15-17.) This is an important point of contention in the present appeal.

As stated previously, one of ordinary skill in the art would recognize that suitability of an alloy for use in an endoprosthesis would depend on many factors, such as torsional strength, minimization of re-stenosis, or minimization of inflammation. Additionally, for example, one of ordinary skill in the art would recognize that certain magnesium alloys would degrade too quickly or would degrade with an accompanying evolution of gas. (See, for example, U.S. Pat. No. 3,687,135, column 1, lines 38-56). Suitability for use in blood vessels would certainly include a lack of gas production, since formation of gas bubbles in the bloodstream could cause a gas embolism. As stated previously, none of the cited prior art references provide any teaching or suggestion as to the suitability of the claimed compositions as an endoprosthesis.

In fact, there are a variety of magnesium alloys that would not be considered suitable for use as an endoprosthesis by one of ordinary skill in the art. These include magnesium-aluminum alloys (as mentioned above, see U.S. Pat. No. 3,687,135, column 1, lines 38-56), and alloys containing “lead, beryllium, copper, thorium, zinc, nickel, etc.” (U.S. Pat. No. 3,687,135, column 2, lines 13-15).

The Examiner concluded, “it would have been obvious to one having ordinary skill in the art at the time the invention was made to try the well known magnesium alloy, as evidenced by Unsworth, in Wu’s stent.” (page 6, lines 3-5). For an obviousness rejection to be proper under the “obvious to try” rationale, the Examiner must establish:

- (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;
- (2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;
- (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

Failure to establish any of these factors indicates that an obviousness rejection is not proper. (Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v Teleflex Inc.*, Federal Register, Vol. 72, No. 195, 57526, 57532, October 10, 2007).

As provided above, one of ordinary skill in the art would have found no guidance as to the suitability of the claimed alloy composition in an endoprosthesis. Therefore one of ordinary skill in the art could not have pursued the combination of the claimed alloy composition with

Wu's stent with a reasonable expectation of success. Furthermore, given the general nature of Wu's disclosure of magnesium alloys, and the number of possible combinations with other metals to form a magnesium alloy, it can not be said that there was "a finite number of identified, predictable potential solutions to the recognized need or problem." Wu's general disclosure of magnesium alloys includes a virtually limitless number of alloys.

Therefore, it is impossible to conclude that a person having ordinary skill in the art would have found a teaching or suggestion, either in the cited prior art or in the knowledge generally available, that a magnesium alloy containing yttrium as claimed is compatible with use in an endoprosthesis.

CONCLUSION

The Applicants respectfully assert that all of pending claims 1-37 are allowable for at least the following reasons:

One of ordinary skill in the art would not have found any suggestion to modify Wu or to combine Wu with Unsworth or Richter to use a magnesium alloy as disclosed by Unsworth as an a magnesium alloy in a stent of Wu. One of ordinary skill in the art would have had no reasonable expectation of success in combining the teachings of the references as suggested by the Examiner. Such a suggestion to combine the references or expectation of success in making the combination can only be the result of impermissible hindsight.

In accordance with the foregoing, the Applicants respectfully request reversal of the Examiner's decision rejecting the claims and allowance of all claims. This Reply Brief is timely filed on or before January 26, 2009. No fees are believed to be due with this Reply Brief. However, in the event that a fee for the filing of this paper is required, the Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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